

## REMARKS/ARGUMENTS

Claims 1-16, which are directed to a process for producing tiacumicins, have been elected and examined. Unelected claims 17-27 are cancelled by the present Amendment. Claims 1-16 have been cancelled and substituted with claims 28-40.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph. Claim 6 (now claim 33) is directed to a process for producing Tiacumicins comprising culturing the microorganism, *Dactylosporangium aurantiacum* NRRL 18085. The Examiner has requested confirmation that *Dactylosporangium aurantiacum* was available to the public at the time of invention. On page 8 of the specification, it is stated that the microorganism with an assigned accession number of NRRL 18085 was obtained from a particular research center, the Agricultural Research Service (ARS) Culture Collection located in Peoria, Illinois. Based on the Manual of the Patent Office, that center is a depository recognized and acceptable to the Patent Office. On January 9, 2008 the undersigned contacted Mr. James Swezey, the curator at the ARS Culture Collection, and Mr. Swezey confirmed that the microorganism, *Dactylosporangium aurantiacum*, with the accession number of NRRL 18085 was publicly available from that center at the time of the present invention. Additionally, a copy of a letter dated September 5, 2001 sent by Mr. Swezey to a research entity in Taiwan indicates that at the ARS Culture Collection was providing a sample of *Dactylosporangium aurantiacum* NRRL 18085, and that it does not place restrictions on strains released and distributed to the public. A copy of this letter is enclosed with the present Amendment.

Accordingly, it is respectfully requested that the rejection of claim 6 under 35 U.S.C. 112, first paragraph, be withdrawn.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. The Examiner states that claim 1-5 do not recite any process parameters, while the remaining claims are unclear. Claims 1-16 have been substituted with new claims 28-40 to address this rejection.

Claims 1-4, 6, 9-12 are rejected under 35 U.S.C. 102(a) as anticipated by Hochlowski et al., J. Antibiotics 40: 575-588, 1987. The new claims 28-40 recite the use of an absorbent resin, which is not taught or suggested by Hochlowski. The amendment to the claims renders this rejection moot. It is respectfully requested that the rejection of Claims 1-4, 6, 9-12 under 35 U.S.C. 102(a) as anticipated by Hochlowski be withdrawn.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as obvious over the combination of Hochlowski, and Coronelli et al. (U.S. Patent 3,978,211), Waters et al. (U.S. Patent 4,632,902) Hoefle et al. (U.S. Patent 7,067,544) and Demain et al., Manual of Industrial Microbiology and Biotechnology, American Society of Microbiology, Washington, D.C. 1989, pp 123-126. Claims 1-16 have been cancelled in favor of new claims 28-40.

Hochlowski, Coronelli and Waters do not disclose the use of a resin during the culturing of the microorganism. Further, Coronelli does not disclose the production of tiacumicins but rather lipiarmycin.

Only Hoefle and Water discuss the use of a resin. In Hoefle, the resin XAD-16 is used during fermentation so that epothilones that are produced by fermentation are absorbed. Epothilones as described in Hoefle are very different in chemical structure to tiacumicins, and there is no teaching in Hoefle or any of the other cited references that tiacumicins can be similarly absorbed by a resin during fermentation. Water teaches the use of a resin to absorb antibiotics from a body fluid specimen without removal of the infecting bacteria contained in the specimen. Such absorption occurs in an environment that is different from that encountered during fermentation. Accordingly, there is no reasonable basis to combine Water with the principal reference, Hochlowski, to suggest the presently claimed process.

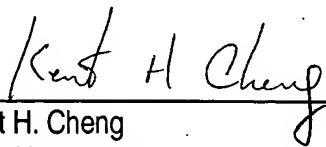
Additionally, the presently claimed process exhibits unexpected results. Applicants have found that the use of an absorbent resin in the nutrient medium during the culturing of the microorganism unexpectedly resulted in a change in the profile of the fermentation product by increasing the production of R-tiacumycin B and suppressing the other related tiacumicins.

Accordingly, it is respectfully requested that the rejection of claims 1-16 (now claims 28-40) under 35 U.S.C. 103(a) as obvious over the combination of Hochlowski, and Coronelli, Waters, Hoefle and Demain be withdrawn.

It is believed that no fees or charges are required at this time in connection with the present application. However, if any fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No..03-2412.

Respectfully submitted,  
COHEN PONTANI LIEBERMAN & PAVANE LLP

By \_\_\_\_\_

  
Kent H. Cheng  
Reg. No. 33,849  
551 Fifth Avenue, Suite 1210  
New York, New York 10176  
(212) 687-2770

Dated: February 28, 2008



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United States  
Department of  
Agriculture

Agricultural  
Research  
Service  
Midwest Area

National Center  
for Agricultural  
Utilization Research

1815 North University Street  
Peoria, Illinois 61604  
Telephone: 309-681-6560  
Fax: 309-681-6672

ARS CULTURE COLLECTION (NRRL) WEBSITE  
<http://nrrl.ncaur.usda.gov>

September 5, 2001

Dr. Ming-Hsi Chiou  
Culture Collection and Research Centre  
Food Industry Research & Development Institute  
PO Box 246  
Hsinchu, 300 Taiwan

Dear Dr. Chiou:

In response to your recent request, I am sending, under separate cover, a lyophilized preparation of:

NRRL 18085

*Dactylosporangium orrantiacum*

It should be known that this strain was deposited in this International Depositary Authority to meet the requirements of the U. S. Patent Office and certain other foreign property offices. The ARS Culture Collection does not place restrictions on strains released and distributed to the public. However, any commercial or other unauthorized use of these strains without the consent of the depositor could involve patent infringements.

The Agricultural Research Service Patent Culture Collection is now required to charge \$20.00 for all strains deposited after October 30, 1983 (strains with numbers of 15723 or higher). This fee was established at the same time we began charging for the deposition of strains into the patent collection (\$500). There is no charge for strains in the open collection (strains not connected with patent applications) and strains deposited into the patent collection before October 30, 1983.

I will have our Budget and Fiscal Office send an invoice for \$20.00. Checks in U.S. dollars should be made payable to the Agricultural Research Service, U.S. Department of Agriculture.

Please acknowledge the safe receipt of this shipment.

Sincerely,

J. L. Swezey, Curator  
ARS Parent Culture Collection  
Microbial Genomics and Bioprocessing Research Unit  
Tel: (309) 681-6398  
Fax: (309) 681-6672  
Email: [swezeyjl@mail.ncaur.usda.gov](mailto:swezeyjl@mail.ncaur.usda.gov)